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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,252	02/27/2007	Freda D. Miller	50037/003003	3359

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CLARK & ELBING LLP  
101 FEDERAL STREET  
BOSTON, MA 02110

EXAMINER
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BARNHART, LORA ELIZABETH

ART UNIT	PAPER NUMBER
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1651

NOTIFICATION DATE	DELIVERY MODE
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06/16/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/587,252	<b>Applicant(s)</b> MILLER ET AL.	
	<b>Examiner</b> Lora E. Barnhart	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

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### **DETAILED ACTION**

Claims 1-68 as originally filed are currently pending.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, and 5-20, drawn to a method of producing multipotent stem cells from a hair follicle comprising sorting cells by their adherence to a culture substrate.

Group II, claim(s) 3, 5-25, and 42-52, drawn to a method of inducing hair growth in a mammal by providing to said mammal multipotent stem cells that are capable of producing hair follicle cells.

Group III, claim(s) 4-25, drawn to a method of inducing hair growth in a mammal by providing to said mammal cells that have differentiated from multipotent stem cells.

Group IV, claim(s) 26-33, drawn to a composition comprising multipotent stem cells capable of inducing hair growth in a mammal.

Group V, claim(s) 34-41, drawn to a composition comprising multipotent stem cells capable of inducing skin growth in a mammal.

Group VI, claim(s) 53-63, drawn to a method of regenerating skin in a mammal by providing to said mammal multipotent stem cells that are capable of regenerating skin.

Group VII, claim(s) 64-68, drawn to a method of making hair follicles comprising culturing multipotent stem cells such that they differentiate into hair follicles.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature that unifies the Groups does not make a contribution over the prior art.

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Li et al. (2003, U.S. Patent Application Publication; reference A) teaches multipotent stem cells isolated from hair follicles that can give rise to differentiated cells including keratinocytes and can be used to regenerate skin (paragraphs 22, 30, 49, and 51-53). Furthermore, Tankovich et al. (2000, U.S. Patent 6,050,990; reference B) teaches stem cells isolated from dermal papilla (bulge area) that can be used to regenerate follicles (column 56, line 12, through column 58, line 10). Because the compositions of Groups IV and V were known in the art at the time of the invention, they cannot be considered a special technical feature.

Finally, an international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) a product and a process specially adapted for the manufacture of said product; (2) a product and a process of use of said product; (3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; (4) a process and an apparatus or means specifically designed for carrying out the said process; or (5) a product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. **If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims.** See 37 C.F.R. 1.475.

For at least the aforementioned reasons, restriction among Groups I-VII is proper.

Claims 5-20 are linking claims that are multiple dependents of claims 1, 3, and 4. Claims 21-25 are linking claims that are multiple dependents of claims 3 and 4. If Group I, II, or III is chosen, these claims will be examined to the extent that they read on the elected group. See M.P.E.P. § 809.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Proteins expressed by stem cells: (a) nestin, (b) WNT-1, (c) vimentin, (d) fibronectin, (e) S 100, (f) slug, (g) snail, (h) twist, (i) Pax3, (j) Sox9, (k) Dermo, and (l) SHOX2, as in claims 8, 28, 36, 47, 58, and 66; elect ONE.

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Proteins not expressed by stem cells: (m) tyrosinase, (n) c-kit, (o) tryp1, (p) DCT, (q) MBP, (r) P0, (s) SOX10, and (t) p75NTR, as in claims 9, 10, 29, 30, 37, 38, 48, 49, 59, 60, 67, and 68; elect ONE.

Endpoints of differentiation: (u) neurons, (v) astrocytes, (w) Schwann cells, and (x) oligodendrocytes, as in claim 15; elect ONE.

Genetic state of cells: (y) not containing any exogenous DNA constructs and (z) containing a construct with exogenous DNA, as in claims 18-20; elect ONE.

Conditions: (a') alopecia, (b') accidental injury, (c') damage to hair follicles, (d') surgical trauma, (e') a burn wound, (f') radiation therapy, (g') chemotherapy, (h') an incisional wound, and (i') a donor site wound from skin transplant, as in claims 25, 32, 40, 51, and 62; elect ONE.

Applicant is required, in reply to this action, to elect a single species from each of the above lists to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: claims 1-7, 11-14m 16m 17, 21-24, 26, 27, 31, 33-35, 37, 39, 41-46, 50, 52-57, 61, and 63-65.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Pursuant to PCT Rule 13.2 and PCT Administrative Instructions, Annex B, Part 1(f)(I)(B)(2), the species are not art-recognized equivalents. When alternatives of chemical compounds are claimed, they shall be regarded as being of a similar nature where all alternatives have a common

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property or activity, and either a significant structural element is shared by all of the alternatives, or all of the alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains. The words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together. The words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

In this case, the proteins in (a)-(l) do not appear to share a common core structure; the proteins in (m)-(t), likewise, do not have similar amino acid sequences. These proteins have diverse properties and activities and could not be substituted one for the other. The endpoints of differentiation in (u)-(x) represent four divergent cell types that have diverse actions and display different expression patterns of characteristic markers. Cells including exogenous DNA do not necessarily have a common activity with those cells that do not; expressing an exogenous protein may change the properties and gene expression profiles of a cell. Finally, the conditions in (a')-(i') represent patient sets that do not overlap and, therefore, cannot be substituted one for the other.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

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patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is (571)272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/  
Primary Examiner, Art Unit 1651